Saskatchewan
Labour

Occupational
Health & Safety

Needle Safe Devices and Improved Exposure Control Plans

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PLEASE NOTE

The original statutes, as published in the bound and sessional annual volumes, and the regulations, as published in Parts II and III of *The Saskatchewan Gazette*, should be consulted for all purposes of interpretation and application of the law.

To purchase copies of *The Occupational Health and Safety Act, 1993* or its regulations, contact the Queen's Printer in Regina at (306) 787-6894. The FAX number is (306) 787-9779. The website is www.qp.gov.sk.ca

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106-05346/

Introduction

Changes to *The Occupational Health and Safety Regulations, 1996* have been introduced to reduce puncture injuries of health care and other workers who use needles and other sharps. There are changes to section 85 that improve on the existing requirement for an exposure control plan and changes in Part XXXI (Additional Protection for Health Care Workers).

This guide is for health care (including blood collection agencies) and correctional facilities and is meant to:

- interpret and explain the new duties of employers, contractors and self-employed persons,
- assist workplace parties in preparing improved written exposure control plans by January 1, 2006, and
- assist workplace parties in identifying, evaluating, selecting and using safer needle devices by July 1, 2006.

The New Regulations

The new regulations that came into effect October 18, 2005:

1. Require all employers, in consultation with their occupational health committee(s) (OHC), to adapt and implement written exposure control plans by January 1, 2006, to:
    - describe how Needle Safe Devices (NSDs) will be evaluated, selected and in use by July 1, 2006, in health care and correctional facilities (by July 1, 2007, for blood collection agencies and other national programs that require a Health Canada approval to make the change),
    - describe how representatives of workers or self-employed persons who will use the devices will be consulted in their identification, evaluation and selection,
    - describe how affected workers will be trained before July 1, 2006, and

- address other new requirements in section 85 such as:

  i. training workers on the use of engineering controls (including NSDs and sharps safe devices (SSDs)) and other infection control measures prior to their performing tasks that put them at risk of exposure, and

  ii. ensuring that new types of NSDs and SSDs and other infection control measures are identified and evaluated and considered for selection on an ongoing basis.

2. Mandate the use of NSDs in health care facilities and correctional facilities by July 1, 2006 (or July 1, 2007, as noted above), except where:

   - they pose a risk to patients/workers/self-employed persons,
   - the health care facility is a veterinary facility, or a private medical or dental office/clinic,
   - the needles were purchased before October 18, 2005 for a public health emergency,
   - it is an injection ready needle device containing an antibiotic or biological product that was purchased prior to October 18, 2005, or
   - the needle is purchased during a public health emergency.

3. Require employers or contractors to keep a sharps injury log.

The full text of the new regulations can be found in Appendix 1.

The Need for Change - Why New Regulations?

Needlestick injuries, as well as other sharps-related injuries (sharps injuries), can be a significant risk for health care and other workers. Some of these injuries can expose workers to bloodborne infections that are potentially life threatening, such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV). After a sharps injury, prolonged follow-up testing may be required, with considerable emotional impact on both the worker and his/her family regardless of test results. The financial implications of such an injury can also be extraordinary, particularly if the exposed worker eventually develops a disease and requires life-long treatment.

Fortunately, there have been significant improvements in the design of devices that help prevent sharps injuries and many workplaces have begun to introduce the use of NSDs and other SSDs. New regulations will build on these efforts and accelerate the change to safer devices.

In a 2002 report, *Prevention and Control of Occupational Infections in Health Care*, Health Canada concluded that using safety-engineered needles or needleless alternatives significantly decreases the number of needlestick injuries in health care settings. Such injuries have been reduced by more than 50% and, in some cases, more than 80% when hollow-bore needles were replaced with safety-engineered alternatives.

The same report recognized evidence that early attempts to reduce sharps injuries using safety guidelines and training were not successful. Health Canada further recognized that replacing conventional needles with safety-engineered alternatives would be a more effective control strategy. This is consistent with the hierarchy of controls principle of occupational health and safety in that an engineering control that removes a hazard is the preferred first line of control. Only when an engineering control cannot be used, should less effective controls be relied upon.

Currently, there is no comprehensive system in Saskatchewan to record all sharps injuries, but proponents of the use of SSDs have used sharps injury rate data in a small number of hospitals to estimate that approximately 2000 sharps injuries occur per year in Saskatchewan. In one year (2002), the Saskatchewan Association of Health Organizations (SAHO) received 661 voluntary reports of sharps injuries from some participating health care facilities.

In the same time period, the Workers' Compensation Board (WCB) accepted 286 claims for puncture injuries in the health care sector (308 in 2003; 299 in 2004). WCB has accepted one work-related claim for HIV and a small number of claims for hepatitis that were related to puncture injuries.

Developing Improved Exposure Control Plans

Section 85 of the regulations require the employer, in consultation with the OHC, to develop and implement a written exposure control plan. This plan is for any workers required to handle, use or produce an infectious material or organism or who are likely to be exposed[1] to an infectious material or organism at a place of employment. Changes to this section need to be addressed before January 1, 2006.

The adequacy of the exposure control plan must be reviewed every two years and whenever necessary to reflect changes in infection control measures, including SSDs. This must be done in consultation with the OHC.

All required elements of the section 85 Written Exposure Control Plan are listed in Appendix 1. The following sections describe what should be included in these elements to address sharps injury prevention.

I) Identify Workers and Tasks

In this section of the plan, identify workers who use, handle or may otherwise encounter contaminated[2] needles and other sharps, and identify the categories of tasks or procedures that put them at risk.

This means analyzing job positions to identify those that may sustain a contaminated sharps injury. Refer to data on job-specific injury rates from your facility, from similar facilities, or from sources such as Health Canada (see references) or EPINet (www.healthsystem.virginia.edu/internet/epinet/). Job positions would include, but are not limited to, nurses, physicians, nursing assistants and aids, housekeeping and laundry staff, laboratory technologists and respiratory therapists.

To identify categories of tasks or procedures that may result in a contaminated sharps injury, consider procedures that include, but are not limited to:

- surgical procedures, injections, and suturing,
- establishing and maintaining intravascular access and/or intravenous manipulation,
- analysis of blood or body fluids,

[1] "Expose" is defined in Appendix 1 to mean harmful contact with an infectious material or organism from inhalation, ingestion, skin or mucous membrane contact or percutaneous injury.
[2] "Contaminated" is defined in Appendix 1 to include fluids that can transmit human bloodborne pathogens.

- recapping or disposing of used needles and other sharps instruments, and
- maintaining, repairing, dismantling or cleaning contaminated equipment.

Also use data from the workplace, Health Canada guidelines (see references), EPINet website, etc. for task-specific sharps injury rates.

II) Describe the Exposure Risks

Describe:

- the ways that infectious material can enter the body,
- the risks (infections, diseases) associated with that entry, and
- signs and symptoms of any disease that may arise from exposure.

For sharps injuries, discuss factors that affect the risk of a bloodborne infection, including:

- how contaminated the puncturing object is,
- the depth of the puncture, and
- the gauge of needle (in needlestick punctures).

Information on symptoms of bloodborne diseases can be found in Health Canada reports, such as *Prevention and Control of Occupational Infections in Health Care,* and pathogen-specific information sheets can be found at www.phac-aspc.gc.ca/msds-ftss/.

III) Describe the Control Measures

Describe control measures for workers who generate, collect, transport, clean, decontaminate or dispose of waste, or launder contaminated laundry. Control measures must include controls related to the use of sharps instruments and needles, and their limitations. Engineering controls are, in most cases, the most effective control measure.

1) Engineering Controls

These are physical controls or barriers that isolate or remove an infectious disease hazard. They include NSDs and other SSDs and sharps disposal containers.

a) Sharps Safety Devices (includes NSDs)

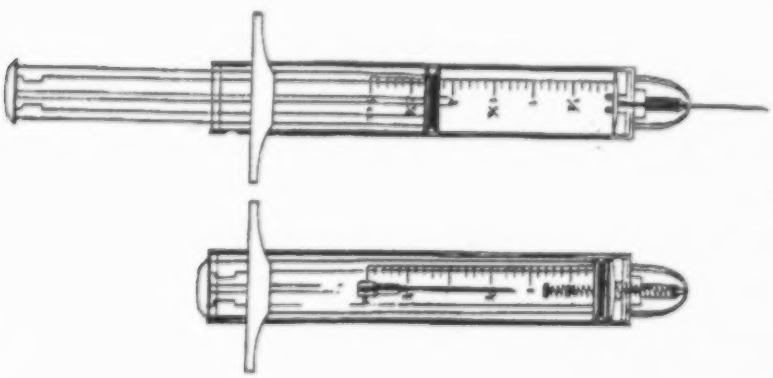
While sharps disposal containers can eliminate the risk of a sharps injury after a sharp is used, SSDs can eliminate the hazard during and after their use.

Sharps safety devices include:

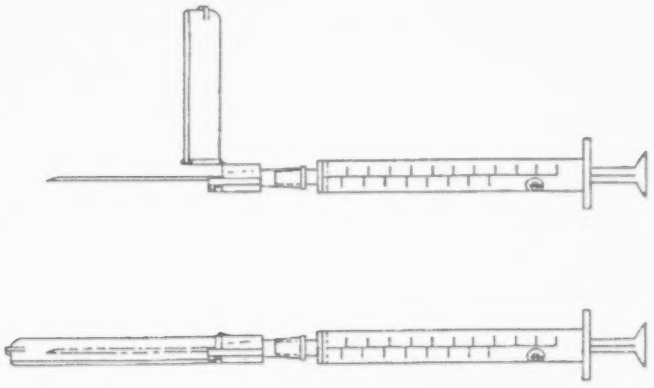
- NSDs such as:
  - needleless systems (e.g., needleless IV connectors)
  - sharps with engineered sharps injury protection (e.g., needles with attached sheaths that cover the needle immediately after use or needles that retract into a device immediately after use) See Figure 1 for examples.
- other SSDs such as blunt suture needles, disposable or reusable sheathing scalpels, self-retracting lancets and the use of plastic (instead of glass) tubes etc.

Figure 1 - Examples of Needle Safe Devices
(Source: U.S. Occupational Safety and Health Association, with permission)

1a. Hypodermic syringes with "Retractable Technology" safety feature



1b. Add-on Safety Feature



By January 1, 2006, this section must describe how NSDs will be identified, evaluated, selected and in use by July 1, 2006, in consultation with representatives of workers and self-employed persons who will use the devices.

By July 1, 2006, section 474.1 requires that NSDs be used in health care facilities and in correctional facilities. They must be used where it is reasonable to anticipate there is a risk of a puncture injury from a contaminated needle.

Although blood collection agencies are now considered health care facilities, the requirement to use NSDs in blood collection agencies is not in effect until July 2007. This is because device changes require a Health Canada approval process that can take over a year. The later date also applies to nationally purchased injection-ready vaccination needles that require Health Canada approvals.

NSDs are required when a needle safe alternative is commercially available. A commercially available NSD is one that is available for purchase in the marketplace, designed for the purpose for which it will be used and has been approved by Health Canada.

NSDs are not required in the rare case that a commercially available NSD safe device may pose an additional risk to a patient, worker or self-employer person. An additional risk is one that endangers a patient, worker or self-employed person, and would not include additional minor discomfort to the patient, or clinical inconvenience, such as slowness or initial awkwardness of use, that have no implications for patient or worker health. When NSDs cannot be used, workers must be protected by other effective control measures.

There are exceptions for a few other circumstances. A number of vaccines, anti-virals and other biological products have been stockpiled for public health emergencies[3] or for lower risk vaccination programs. Those purchased before October 18, 2005 can still be used. If purchased after October 18, 2005, these injection-ready medications must be safe-engineered versions, if such alternatives are commercially available. Many injection-ready biological products may not be commercially available in Canada, if the only supplier is a single international manufacturer.

It is anticipated that supplies of needles will be rapidly exhausted and difficult to acquire during a public health emergency. For this reason, the requirement does not apply to needles purchased during such an event.

To identify NSDs and other SSDs, first identify what is commercially available. Options for commercially available SSDs are continually expanding. A number of agencies, such as EPINet of the University of Virginia, maintain a list of available devices and their manufacturers (see www.healthsystem.virginia.edu/internet/epinet/safetydevice.cfm). Next, determine the devices that are approved by Health Canada for use in Canada. Ask the supplier for the Health Canada Medical Device Number. You can then check to see if the medical license number or product trade name is listed on the following web-site www.mdall.ca/. This site is a listing of all devices with active medical licenses in Canada.

A comprehensive program is needed to evaluate and select safer devices in a systematic manner. Ideally, the product choice should be based on:

- The needs of the primary users. Employers or contractors must consult representatives of workers and self-employed persons who will use the devices. This is critical to ensure workers accept the use of the new devices.
- The needs of the patients who must continue to receive safe, efficient, and comfortable care. Health care workers are likely to reject products that they think will interfere with patient care in any way.

The following has been suggested as elements of a comprehensive program *(Chiarello, 1995)*:

- creation of a multi-disciplinary team,
- defining prevention priorities on the basis of collection and analysis of an institution's injury data,

[3] A "public health emergency" is defined in the regulations and means an occurrence or imminent threat of a significant risk to public health caused by (i) an epidemic or pandemic disease, or (ii) a novel, highly fatal infectious agent or associated biological toxin.

- developing design and performance criteria for product selection according to needs for patient care and health care worker safety,
- using an evaluation tool (see Appendix 2 for an example),
- planning and implementing an evaluation of products in clinical settings,
- analyzing product performance and cost-effectiveness to choose the product,
- listing the types of options available, and
- using "trial periods" for workers to become familiar with new technologies and for workers to provide feedback.

The US Food and Drug Administration (FDA, 1992, 1995) has suggested that a safety feature designed to protect health care workers should:

- provide a barrier between the hands and the needle after use,
- allow or require the worker's hands to remain behind the needle at all times,
- be an integral part of the device and not an accessory,
- be in effect before disassembly and remain in effect after disposal to protect downstream workers, and
- be simple and self-evident to operate and require little or no training to use effectively.

The types of safety features used in NSDs can be categorized according to certain aspects of the safety feature, i.e., whether the feature is active or passive and whether the engineering control is part of the device *(Chiarello, 1995)*.

Passive safety features remain in effect before, during and after use; health care workers do not have to activate them. Passive features enhance the safety design and are more likely to have a greater impact on prevention.

Active devices require the health care worker to activate the safety mechanism. Failure to do so leaves the worker unprotected. Proper use by health care workers is the primary factor in the effectiveness of these devices.

An **integrated safety design** means that the safety feature is built in as an integral part of the device and cannot be removed. This design feature is preferred.

An **accessory safety device** is a safety feature that is external to the device and must be carried to, or temporarily, or permanently fixed to the point of use. This design is also dependent on worker compliance and, according to some researchers, is not desirable.

Although employers are not required to implement the most technically advanced engineering controls, they are required to regularly evaluate the effectiveness of existing controls and to review the feasibility of instituting more advanced engineering controls. The employer must review the adequacy of the exposure control plan, and amend it if necessary at least every two years or more, or more frequently, to reflect advances in infection control measures, including SSDs. For example, a review is needed if a new class of Health Canada approved SSDs become commercially available.

No single NSD will work equally well in every setting, so employers and contractors must develop a comprehensive program to select the most appropriate device considering the setting. The goal is to choose devices that are:

- clinically effective,
- acceptable to users, and
- effective in reducing needlestick injuries in that particular setting.

The plan should indicate that old stocks of conventional sharps devices be removed to prevent workers and self-employed persons from continuing to use them.

b) Sharps Containers

Sharps containers must be provided and made readily accessible at their point of use. Containers need to be an appropriate size and design for the items being disposed of. These items include waste needles, syringes, blades, clinical glass and any other clinical items that are capable of causing a cut or puncture in health care facilities. Employers must take steps to ensure that workers and self-employed persons use those containers.

The containers must be labeled as hazardous waste and have a fill line. They need to be sturdy enough to resist puncture under normal conditions of use until the containers are disposed of. Container lids must be sealed prior to disposal of the container.

2) Vaccinations

Vaccinations are effective control measures that can prevent certain infectious diseases, such as HBV, in the event of an exposure. Vaccinations do not protect against all bloodborne pathogens, as they are only available for a limited number of bloodborne pathogens.

Employers need to ensure that workers who may be exposed to an infectious material or organism are informed of vaccines recommended in the *Canadian Immunization Guide* by a Medical Health Officer or by a physician with expertise in immunization or the control of infectious disease.

The employer must offer these vaccines, arrange for workers to be vaccinated during work time, and cover associated costs. See *Guide to Vaccinations in the Workplace* (listed in References) published by Saskatchewan Labour for information on what vaccinations are recommended for health care workers and for more information on employer duties.

3) Safe Work Practices and Procedures

Safe work practices and procedures are important, and often inexpensive control measures do help reduce the likelihood of injuries from needles or other sharps devices. Such measures are needed for workers who generate, collect, transport, clean, decontaminate or dispose of waste, or who launder contaminated laundry. Examples of safe work practices and procedures would include:

- No recapping of unsheathed or used needle (regular type)

  The procedure of manually recapping used or unsheathed contaminated needles (often prior to disposal) poses a significant risk of injury. Employers must ensure that workers do not manually clip, bend, break or recap waste needles.

- Use of sharps disposal containers

  Sharps disposal containers allow for the safe disposal of sharps and help prevent sharps-related injuries. Ensure these containers are close at hand. For example, containers should be in the immediate vicinity when injections are being made and not kept just in hallways or other centralized locations.

- Housekeeping procedures/dealing with waste[4]

  Ensure there are procedures for handling full sharps disposal containers and for dealing with wastes (e.g., cleanup procedures for broken glassware). Where worker exposure to waste is likely to occur, section 472 of the regulations require a health care employer to develop and implement a process that ensures the waste is:

  a) segregated near where it is generated,

  b) safely contained in a labeled and secure container until it is cleaned, decontaminated or disposed of, and

  c) cleaned, decontaminated or disposed of in a manner that will not endanger the health or safety of any worker.

  Section 472 also requires the employer to ensure that workers or self-employed persons who may be exposed to waste or contaminated laundry:

  a) are trained in safe work practices and procedures, provided with personal protective equipment that is appropriate to the risks associated with the work, and

  b) follow the safe work practices and procedures and use the personal protective equipment

- Decontamination

  Health care employers need to ensure that, where reasonably practicable, any equipment that has been contaminated with waste is inspected and decontaminated before it is repaired or shipped for repair (section 474).

- Practices that incorporate "universal" precautions

  Procedures, such as routine, standard or body substances precautions, must assume that blood or other body fluids or tissues are infectious.

[4] For more information on biomedical wastes, refer to the *Saskatchewan Biomedical Waste Management Guidelines*.

IV) Describe Post Exposure Procedures and Actions

Written procedures are needed to address what steps are taken in the event of an exposure or a suspected exposure, such as:

1. Immediate first aid and evaluation procedures. These procedures will include the names and phone numbers of key contacts.
2. Immediate medical evaluation and intervention by a qualified person. Include how the need for post-exposure prophylaxis will be determined and provided.
3. Seeking the infection and/or immune status of the worker and source patient (if applicable) after obtaining consent.
4. Source and worker testing, if necessary. Patient consent is required for source testing unless it is judged to be mandatory under the *Saskatchewan Mandatory Testing and Disclosure (Bodily Substances) Act*. www.saskjustice.gov.sk.ca/legislation/summaries/manditorytesting.shtml
5. Confidential post-exposure counseling.
6. Measures that ensure patient and source confidentiality.

It is an employer duty to ensure, with the worker's consent, that immediate medical evaluation, medical intervention and post-exposure counseling are provided by a qualified person and in the manner described in *Guidelines for the Management of Potential Exposures to Hepatitis B, Hepatitis C, HIV and Recommendations for Post-Exposure Prophylaxis*, Saskatchewan Health.

If this cannot be done on work time, the employer must credit the worker's attendance for the above as time at work and ensure the worker does not lose pay or other benefits.

Written procedures are also needed to describe the procedures that will be used to investigate and document work-related exposures and cases of infectious diseases. These will include procedures to identify the route and circumstances of the exposure and procedures to determine and implement measures to prevent future occurrences.

Health care employers and contractors must now keep a log of potentially contaminated needlestick and other sharps injuries to identify risk factors (new section 474.2). This must be done in a manner that respects the confidentiality of the exposed worker or self-employed person and any source persons. At minimum the log must include:

i. the type and brand of the device involved in the incident,

ii. the department or work area in which the exposure occurred, and

iii. an explanation of how the exposure occurred.

Record keeping and analyses can now be done readily using standardized methods and software provided free of charge through the Exposure Prevention Information Network (EPINet), University of Virginia www.healthsystem.virginia.edu/internet/epinet/about_epinet.cfm

The explanation of how the exposure occurred should include:

- location and time of event,
- nature of the event – "what happened",
- control measures in place at the time of the event,
- work practices and procedures followed,
- personal protective equipment used at the time, and
- history of worker training (had training been provided).

The data collected must be stored in a fashion that is secure and confidential. Anonymous group data should be made available to the OHC or representative and used when reviewing new technology needs. This data can provide a valuable tool to assist employers, contractors and the committee to:

- prevent similar occurrences in the future,
- determine where NSDs are needed, and
- determine where more effective control measures are needed.

"The collection and evaluation of complete needlestick injury data by health care facilities are key to identifying injury patterns and then implementing an effective abatement plan." (Chiarello, 1995)

V) Describe Worker Training

The plan must describe the training that will be provided to workers who may be exposed to infectious materials or organisms and the means by which this training will be provided. The regulations define "train" as "to give information and explanation to a worker with respect to a particular subject matter and require a practical demonstration that the worker has acquired knowledge or skill related to the subject matter." Training on the use of SSDs will be needed whenever they are introduced and result in a new process or a change in an existing process.

Describe how workers will be trained before they are required or permitted to undertake any work or tasks identified in the plan. Workers cannot be required or permitted to undertake such work or tasks until they have been trained.

The training would include all the elements of the plans including:

- disease information: exposure risks, transmission characteristics, signs and symptoms,
- vaccinations (if applicable),
- engineering controls,
- the use of personal protective equipment,
- safe work practices and procedures,
- the application of universal precautions, and
- post-exposure protocols and post-exposure counseling.

Training, education, familiarity with and following manufacturers' recommendations are crucial to the effectiveness of SSDs. Evidence indicates that worker satisfaction and confidence with new devices is higher after training. Published evidence (see References 1 and 8) also indicates that unfamiliarity with needleless systems or not using them according to manufacturers' recommendations could result in an increase in bloodstream infections for patients.

Ensuring Standards are Met

From time to time, workers and employers or contractors may disagree on whether exposure control requirements have been met. For example, the employer or contractor may not agree on the NSDs selected. There may also be a dispute as to whether NSDs should be avoided because it is argued to pose an additional risk to a patient.

Role of the Occupational Health Committee

Many disputes can be avoided if the OHC is consulted[5] in the preparation and implementation of the exposure control plan, and if worker representatives are consulted in the identification, evaluation and selection of NSDs.

Role of the Occupational Health Officer

Where the consultation process cannot resolve a dispute, anyone may contact an occupational health officer (officer) for assistance. An officer may intervene to resolve the conflict. If necessary, an officer can issue a notice of contravention requiring the employer (or anyone else covered by the legislation) to take corrective action to comply with the legislation. In making the decision, the officer will apply the principles set out in this guide and seek the advice of independent medical authorities such as the Chief Occupational Health Medical Officer.

Right to Appeal

The decision of an officer to issue a notice of contravention, or not to issue a notice of contravention may be appealed within 21 days of the officer's decision. The appeal is first considered by the executive director of the Occupational Health and Safety Division.

After reviewing the matter based on the officer's investigation and written submissions from interested or informed persons, the executive director may affirm, amend or cancel the officer's decision.

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[5] "Consult" means the employer gives the committee/representative/worker a real opportunity:

- **To be informed** of information essential to making a reasonable and informed assessment,
- **To review and assess** the information and possible alternatives or options,
- **To comment** and/or make recommendations on the possible options and alternatives, and
- **To be considered.** This means the employer will consider the recommendations of the committee or representative and where applicable, give the committee/representative/worker credible reasons for not accepting or implementing the committee's or representative's recommendations.

The executive director's decision can in turn be appealed within 21 days to an independent adjudicator. The adjudicator will hold a hearing into the matter. After the hearing, the adjudicator can amend, affirm or cancel the executive director's decision. A further appeal to the Court of Queen's Bench is permitted, but only on matters related to law or jurisdiction.

Conclusions

Needle and sharps safe devices are essential components of an overall strategy to prevent sharps injuries in health care and other workplaces. To this end, new regulations have been introduced to prevent sharp injuries and improve exposure control plans.

NSDs are required in health care and correctional facilities by July 1, 2006, with some exceptions. Written exposure control plans must be developed in consultation with the OHC by January 1, 2006, to ensure that these devices are identified, evaluated and selected, and in use by July. Representatives of workers who use these devices must be consulted in the selections steps. The plan must also describe how workers will be trained before they are required or permitted to use them.

Training, safe work procedures and the involvement of the committee and workers who use sharps are critical to the selection and effective use of appropriate devices and to the prevention of sharps injuries generally.

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Appendix 1: *The Occupational Health and Safety Amendment Regulations, 2005*

Title

1 These regulations may be cited as *The Occupational Health and Safety Amendment Regulations, 2005*.

R.R.S. c.O-1.1 Reg 1 amended

2 *The Occupational Health and Safety Regulations, 1996* are amended in the manner set forth in these regulations.

Section 2 amended

3 The following clause is added after clause 2(1)(qq):

"(qq.1) **'percutaneous'** means a route of entry that is through the skin or mucous membrane, and includes subcutaneous, intramuscular and intravascular routes of entry".

New section 85

4 Section 85 is repealed and the following substituted:

"Exposure control plan

85(1) In this section:

(a) **'engineering controls'** means physical controls or barriers that isolate or remove an infectious disease hazard and includes:

(i) medical devices approved by Health Canada that have engineered sharps injury protections;

(ii) sharps disposal containers;

(iii) needleless systems and needles with engineered sharps injury protections as defined in section 474.1; and

(iv) other devices that isolate or remove sharps hazards;

(b) **'expose'** means harmful contact with an infectious material or organism from inhalation, ingestion, skin or mucous membrane contact or percutaneous injury;

(c) **'exposure control plan'** means an exposure control plan required pursuant to subsection (2);

(d) **'infectious material or organism'** means an infectious material or organism that has been identified in an approved manner as an infectious disease hazard that poses a significantly increased exposure risk to a worker or self-employed person.

(2) If workers are required to handle, use or produce an infectious material or organism or are likely to be exposed at a place of employment, an employer, in consultation with the committee, shall develop and implement an exposure control plan to eliminate or minimize worker exposure.

(3) An exposure control plan must:

(a) be in writing;

(b) identify any workers at the place of employment who may be exposed;

(c) identify categories of tasks and procedures that may put workers at risk of exposure;

(d) describe the ways in which an infectious material or organism can enter the body of a worker and the risks associated with that entry;

(e) describe the signs and symptoms of any disease that may arise for a worker exposed at the place of employment;

(f) describe infection control measures to be used, such as the following:

(i) vaccination;

(ii) engineering controls;

(iii) personal protective equipment;

(iv) safe work practices and procedures; and

(v) standard practices that incorporate universal precautions;

(g) identify the limitations of the infection control measures described pursuant to clause (f);

(h) set out procedures to be followed in each of the following circumstances:

(i) if there has been a spill or leak of an infectious material or organism;

(ii) if a worker has been exposed;

(iii) if a worker believes that he or she has been exposed;

(i) set out the methods of cleaning, disinfecting or disposing of clothing, personal protective equipment or other equipment contaminated with an infectious material or organism that must be followed and indicate who is responsible for carrying out those activities;

(j) describe the training to be provided to workers who may be exposed and the means by which this training will be provided;

(k) require the investigation and documentation, in a manner that protects the confidentiality of the exposed worker, of any work-related exposure incident, including the route of exposure and the circumstances in which the exposure occurred; and

(l) require the investigation of any occurrence of an occupationally transmitted infection or infectious disease to identify the route of exposure and implement measures to prevent further infection.

(4) If subsection 85(2) applies to an employer on the day on which this section comes into force or at any time before January 1, 2006, that employer must, no later than January 1, 2006, describe in his or her exposure control plan the steps that will be taken by July 1, 2006 to ensure compliance with this section and, if applicable, subsection 474.1(3).

(5) No employer shall allow a worker to undertake any tasks or procedures mentioned in clause (3)(c) unless the worker has been trained with respect to the exposure control plan and the use of control measures appropriate for the task or procedure undertaken.

(6) An employer, in consultation with the committee, shall review the adequacy of the exposure control plan, and amend the plan if necessary, at least every two years or as necessary to reflect advances in infection control measures, including engineering controls.

(7) An employer shall make a copy of the exposure control plan and any amendments to that plan readily available to every worker who may be exposed.

(8) An employer shall:

(a) inform workers who are required to handle, use or produce an infectious material or organism or who may be exposed at a place of employment:

(i) of any vaccine recommended for workers with respect to that risk in the *Canadian Immunization Guide*, published by Health Canada, and recommended by:

(A) a medical health officer appointed pursuant to *The Public Health Act* or a designated public health officer within the meaning of *The Public Health Act, 1994* whose powers and responsibilities include those set out in Part IV of *The Public Health Act, 1994*; or

(B) a physician with expertise in immunization or the control of communicable diseases; and

(ii) of the risks associated with taking a vaccine mentioned in subclause (i);

(b) with the worker's consent, arrange for the worker to receive any vaccination recommended pursuant to subclause (a)(i) during the worker's normal working hours and reimburse the worker for any costs associated with receiving the vaccination; and

(c) if a worker cannot receive a vaccination mentioned in subclause (a)(i) during the worker's normal working hours, credit the worker's attendance for the vaccination as time at work and ensure that the worker does not lose any pay or other benefits.

(9) If a worker has been exposed to blood or potentially infectious bodily fluids at a place of employment, an employer shall, with the consent of the worker, during the worker's normal working hours, arrange for immediate medical evaluation and intervention by a qualified person in an approved manner and for confidential post-exposure counselling.

(10) If a worker cannot receive medical evaluation, medical intervention or post-exposure counselling during the worker's normal working hours, an employer shall credit the worker's attendance for evaluation, intervention or counselling as time at work and shall ensure that the worker does not lose any pay or other benefits.

(11) Nothing in these regulations prohibits an employer or contractor from purchasing supplies in bulk together with another employer or contractor but each employer or contractor is responsible for ensuring his or her compliance with these regulations".

Section 468 amended

5 Clause 468(b) is amended:

(a) by striking out "or" **after subclause (xv): and**

(b) by adding the following after subclause (xv):

"(xv.1) a blood collection agency; or".

Section 474 amended

6 Subsection 474(2) is repealed and the following substituted:

"(2) The containers required by subsection (1) must:

(a) have a fill line;

(b) be clearly identified as containing hazardous waste; and

(c) be sturdy enough to resist puncture under normal conditions of use and handling until the containers are disposed of".

New sections 474.1 and 474.2

7 The following sections are added after section 474:

"Selecting needle-safe devices

474.1(1) In this section and in section 474.2:

(a) **'contaminated'** means contaminated with:

(i) human blood;

(ii) fluids containing visible amounts of human blood;

(iii) any of the following potentially infectious human bodily fluids:

(A) semen;

(B) vaginal secretions;

(C) cerebrospinal fluid;

(D) synovial fluid;

(E) pleural fluid;

(F) pericardial fluid;

(G) peritoneal fluid;

(H) amniotic fluid;

(I) saliva;

(J) breast milk;

(iv) fluids from any unfixed tissue or organ, other than intact skin, from a human, living or dead;

(v) cell, tissue or organ cultures, or other solutions, that may contain a human blood-borne infectious organism; or

(vi) fluids from tissues of experimental animals infected with a blood-borne infectious organism from a human source;

(b) **'needles with engineered sharps injury protections'** means hollow bore needles or devices with hollow bore needles that:

(i) are commercially available;

(ii) are approved as medical devices by Health Canada;

(iii) have a built-in safety feature or mechanism that eliminates or minimizes the risk of a percutaneous injury; and

(iv) are used for purposes that include:

(A) withdrawing bodily fluids;

(B) accessing a vein or artery; and

(C) administering medications or other fluids;

(c) **'needleless system'** means a commercially available device approved as a medical device by Health Canada that replaces a hollow bore needle for use in:

(i) the collection of bodily fluids;

(ii) the withdrawal of bodily fluids after initial venous or arterial access is established;

(iii) the administration of medication or fluids; or

(iv) any other procedure in which it is reasonably anticipated that a worker could incur a percutaneous injury with a contaminated hollow bore needle;

(d) **'public health emergency'** means an occurrence or imminent threat of a significant risk to public health caused by:

(i) an epidemic or pandemic disease; or

(ii) a novel, highly fatal infectious agent or associated biological toxin.

(2) This section and section 474.2 apply:

(a) to all health care facilities mentioned in clause 468(b) except those mentioned in subclauses 468(b)(xiii) and (xiv);

(b) to a correctional facility as defined in *The Correctional Services Act*; and

(c) to a youth custody facility as defined in the *Youth Criminal Justice Act* (Canada).

(3) Subject to subsection (4), on and after July 1, 2006, for tasks and procedures in which it is reasonably anticipated that a worker or self-employed person may incur a percutaneous injury from a contaminated hollow bore needle, the employer or contractor must:

(a) identify, evaluate and select needles with engineered sharps injury protections or needleless systems, in consultation with representatives of those workers or self-employed persons who will use the selected device; and

(b) ensure that the needles with engineered sharps injury protections and needleless systems selected pursuant to clause (a) are used.

(4) Subsection (3) does not apply:

(a) if the employer or contractor can demonstrate that needles with engineered sharps injury protections or needleless systems pose an additional risk to the patient, worker or self-employed person;

(b) to any biological or antibiotic product in an injection-ready needle device that is present in Saskatchewan on the day on which this section comes into force;

(c) to any needles or needle devices that are obtained during a public health emergency for use in that emergency;

(d) to needles or needle devices for use in a public health emergency that are stockpiled for use in a public health emergency and are present in Saskatchewan on the day on which this section comes into force; or

(e) if a needle with engineered sharps injury protections or a needleless system requires Health Canada's approval for use in a national program, including blood collection and vaccination programs, until the earlier of:

(i) the day on which Health Canada approves a needle with engineered sharps injury protections or a needleless system for use in a national program; and

(ii) July 1, 2007.

"Injury log

474.2(1) An employer or contractor must maintain an injury log for all exposures involving a percutaneous injury with a sharp that may be contaminated.

(2) Entries in the injury log maintained pursuant to subsection (1) must:

(a) protect the confidentiality of the exposed worker or self-employed person; and

(b) contain at least the following information:

(i) the type and brand of the device involved in the exposure incident;

(ii) the department or work area in which the exposure occurred;

(iii) an explanation of how the exposure occurred".

Appendix amended

8 Table 14 of the Appendix is repealed.

Coming into force

9 These regulations come into force on the day on which they are filed with the Registrar of Regulations.

Appendix 2: Sample Evaluation Form

This form was developed by:

Training for Development of Innovative Control Technology (TDICT)
Trauma Foundation Building 1, Room 300
San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110

For further information or criteria sheets for other types of devices call:
(415) 431-4336

DRAFT

Safety Syringes
Safety Feature Evaluation Form

Date: _____ Department: _____ Occupation: _____

Product evaluating: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question.
Not applicable (N/A) may be used if the question does not apply to this product.

DURING USE:	**Agree**					**Disagree**
1. The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A
2. The safety feature does not interfere with normal use of this product	1	2	3	4	5	N/A
3. Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4. This product does not require more time to use than a non-safety device	1	2	3	4	5	N/A
5. The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
AFTER USE:						
6. There is a clear and unmistakable change (either audible or visible) that occurs when the safety feature is activated	1	2	3	4	5	N/A
7. The safety feature operates reliably	1	2	3	4	5	N/A
8. The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
TRAINING:						
9. The product does not need extensive training to be operated correctly	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions that you feel should be asked regarding the safety/utility of this product?

Saskatchewan Labour
Occupational Health and Safety

Regina Inquiry: 787-4496
6th Floor,
400-1870 Albert Street
S4P 4W1
Toll Free: 1-800-567-7233

Saskatoon Inquiry: 933-5052
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122-3rd Avenue North
S7K 2H6
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www.labour.gov.sk.ca

WorkSafe SASKATCHEWAN

www.worksafesask.ca